GENERAL REVIEW AND ENFORCEMENT POLICIES

DRUG EXPERIENCE REPORTING REQUIREMENTS

Applicants holding approved new animal drug applications are responsible for establishing and maintaining records concerning experience with the drug and Type A Medicated Articles containing the drug and for making reports of those experiences (21 CFR 510.300 and 510.301) to the Division of Epidemiology and Surveillance. These reports are known as Drug Experience Reports (DER).

I. Purpose:

This guide summarizes the drug experience reporting requirements of applicants holding approved NADAs.

II. Drug Experience Reporting Requirements:

The following summarizes the requirements in 21 CFR 510.300 and 510.301:

A. The regulations require that applicants, including distributors, holding approved NADAs establish and maintain records and make reports of:

1. Unpublished reports of clinical or other animal experience, studies, investigations or tests conducted or reported to the applicant;

2. Experience, investigations or studies involving the physical or chemical properties of the animal drug;*

*This includes stability data on commercial lots in accordance with the approved stability committment in the new animal drug application.

3. Copies of labeling that accompany the drug and copies of promotional labeling (21 CFR 202.1 (1)(2));

4. Advertising for drugs that are labeled for use by or on the order of a licensed veterinarian (21 CFR 202.1 (1)(1));

5. Quantities of the drug distributed to facilitate assessment of adverse effects;

6. Previously unreported changes described in 21 CFR 514.8(a)(5) and those permitted by CVM Director's letter of February 20, 1987 and May 29, 1992;

7. Mix-ups with the new animal drug or its labeling;

8. Changes or deterioration of the new animal drug or failure of a batch to meet specifications;

9. Unexpected side-effects, injury, toxicity, sensitivity reaction, or unexpected incidence or severity of side-effects associated with chemical use irrespective of attribution to the new animal drug;

10. Failure of new animal drug to exhibit expected pharmacological action.

B. Reports shall be submitted to the Division of Epidemiology and Surveillance at intervals of 6 months for the first year following approval and annually thereafter on items 1-5 above.

C. Reports shall be submitted to the Division of Epidemiology and Surveillance immediately on items 6 and 7 above.

D. Reports shall be submitted to the Division of Epidemiology and Surveillance within 15 working days on items 8, 9 and 10 above.

E. Promotional labeling shall be submitted at the time of initial dissemination and advertisements for prescription drugs at the time of initial publication. However, to avoid unnecessary duplication in reporting, the distributors may send their annual reporting information to the NADA holders who in turn shall compile such information into **one** report and submit to the Division of Epidemiology and Surveillance. The distributor shall submit information directly to the Division of Epidemiology and Surveillance on items 3, 4, 7, 9, and 10 above.

III. Anniversary Date for Filing Drug Experience Reports:

A. The date of the initial new animal drug application approval will constitute the anniversary date for all drug experience reports, except as noted in paragraph III.B.

B. Complete drug experience reports will be filed for each approved new animal drug application. Two or more approved new animal drug applications having the same active ingredient may be combined under one report that includes all the information common to the group and all specific information, including marketing data and labeling seperately for each approved NADA covered (21 CFR 510.300 (b)(4)(ii)). The anniversary date assigned to the group will be that of the first individual new animal drug application approved.

C. Drug experience reports will be required on the established anniversary date.